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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,286	12/21/2001	Michael J. Robarge	9516-048-999	6358
20583	7590	01/22/2004		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017			EXAMINER CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/032,286

Applicant(s)

ROBARGE ET AL.

Examiner

Celia Chang

Art Unit

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants in paper No. 6 dated Oct. 29, 2003 have been entered and considered carefully.

Claims 1-67 and newly added claims 68-70 are pending.

2. The rejection of claims 49-55, 57-59, 63-67 under 35 USC 112 first paragraph is also applicable to the newly added claims 68-70 and is maintained for reason of record.

Applicants argued that the term “*modulation*” is a term well known and unlike the definition asserted by the examiner, does not require the simultaneous enhancement and inhibition of an activity by a single compounds but is achieved by administering a compound. Then, if modulation means the compounds neither enhances nor inhibits, merely administered, then, what “modulation” did the compound achieve? Applicants have been given citations from the art to understand the ordinary level of understanding in this particular art. Mere arguments without factual evidence by the attorney are entitled to little weight. In re Lindner 173 USPQ 356.

The specification while disclosed how to administer the compounds, lacks *guidance* in which compound achieves what i.e. how to pick based on merits the different compounds for the particular utility among the enormous “possibilities” of diverse utility. Especially, the prior art cited in the previous office action clearly stated that the field is very complex and unpredictable and no extrapolation should be made (see Vechiarelli).

3. The rejection of claims 1, 4, 6, 9, 12, 22, 24, 25, 28, 30, 34, 36, 37, 40 under 35 USC 102(b) over Muller WO 98/54170 is maintained for reason of record.

Please note that the proviso, placed the instant claims *specifically* to the anticipatory species of Muller ‘170, see particularly p.20-21, examples 12-14 being drawn to explicitly the R2 is H or alkyl, n=0 compounds where now the proviso limitation dictates.

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4. The rejection of claims 1-67 under 35 USC 103(a) over Muller '517 in view of Muller '170, Bundgaard, Naik CA118 and Smith '117 which is also applicable to claims 68-70, is maintained for reason of record.

The allegation of applicants that the rejection contains "impermissible hindsight" is erroneous. Applicants are urged to consult the previous office action pages 3-4 wherein the explicit teaching, the motivation and reasonable expectation of success were clearly delineated for disclosure and suggestion clearly stated by the "prior art". Contrary to applicants' allegation, no "impermissible hindsight" based on applicants' teaching was ever implied. The "drug" is known, the preparation of prodrug is known, the suggestion which motivate one skilled in the art to prepare a drug into its prodrug was found in Smith '117, col. 4, lines 1-5. The rejection was proper and no impermissible hindsight was used.

5. The rejection of claims 1-67 under 35 USC 103(a) over claims 1-2 of US 6,395,754 or provisional rejection of claims 1-67 over claims 1-12 over copending SN 09/972487 in view of Bundgaard, Naik CA118 and Smith '117 which are also applicable to claims 68-70, are maintained for reason of record.

The gist of applicants' argument is based on the same allegation of hindsight construction which contrary to applicants' allegation was not found.

No terminal disclaimer was filed.

6. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please note that the instantly amended claim 34 is an independent claim. Claim 34, does not contain any definition for  $R^2$ .

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

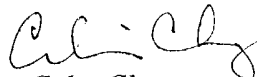
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang  
Jan. 15, 2004

  
Celia Chang  
Primary Examiner  
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